

❖ INTRODUCING

Tim Alexander Toxicology
Amy Buckley Sample Receiving



NOTEWORTHY

✓ ***C. difficile* rapid detection kit:** FDA recently approved BD Diagnostics GeneOhm *C diff* molecular assay to detect the Toxin B gene found in toxigenic *Clostridium difficile*. The molecular assay is done directly on stool samples and can be read in less than 2 hours. The company hopes earlier detection of infection will alert caregivers and prevent disease transmission.

✓ **Point-of-care testing in disaster situations:** The 2004 catastrophic disasters (Southeast Asian tsunami and Hurricane Katrina) showed the need for laboratory testing robust enough to go to the patient in extreme weather conditions. When we take the hand held analyzers outside, how do they perform in harsh temperatures, high (or very low) humidity? Laboratory personnel will find it difficult to control outside weather conditions any time – not just during a disaster.

Researchers from the University of California-Davis studied point-of-care glucose meters and blood gas analyzers in harsh environmental conditions. They stated: “The performance of glucose meter test strips and blood-gas analyzer cartridges was affected adversely and, sometimes inconsistently, by thermal stresses... DMATs and emergency medical responders

should be aware of the potential risks of inaccurate results from POCT when operated in adverse conditions.” This warning applies to paramedics called to accident scenes or search and rescue events. Testing equipment may be left in vehicles that face either extreme heat or freezing temperatures for some time –whether used or not. Such strips and cartridges should be tested frequently with external quality control materials to determine their integrity and ability to achieve accurate test results.

✓ **ESR testing out – C-reactive protein in?** Suzanne Arinsburg, DO and Yash P. Agrawal, MD, PhD at New York Presbyterian Hospital say maybe. Both C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) are non-specific measures of tissue injury and inflammation. While they measure acute-phase patient response differently, they both have a linear relationship in certain diseases. After reviewing several studies, the authors stated in the March 2009 issue of CAP Today that in most cases high-sensitivity CRP could replace ESR for diagnosing acute inflammation.

The authors caution CRP is more expensive and the assay’s linear range is more limited so patients with very high CRP may need their

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samples diluted and retested adding to the cost. At their facility, they offer both tests.

✓ **How is MRSA spreading?** Christa Williams presented her research on the survival of methicillin-resistant *Staphylococcus aureus* (MRSA) on fomites encountered by health students at the 2008 student poster contest for ASCLS in Washington DC. Ms. Williams made MRSA suspensions in McFarland broth, citrated whole blood, and serum. She transferred standard dilutions of MRSA inoculated to the above media to squares of glass, floor vinyl and melamine countertop. After the substrates dried, they were sampled daily with a wet, sterile swab and cultured to determine survival rate. Ms. Williams also cultured 33 student stethoscopes with moistened swabs.

Results: Dried broth MRSA survived for at least 60 days on all surfaces. In serum they survived 41 days on glass, 45 days on tile, and greater than 60 days on countertop. MRSA did not survive in dried, citrated whole blood. Five of the 33 stethoscopes cultured were positive for MRSA. Ms. Williams also found the higher the organism load, the longer the survival. See the entire study in Vol 22 NO 1 Winter 2009 issue of Clinical Laboratory Science.

✓ **Phlebotomy: finding a vein:** Whether you are training phlebotomists, an inexperienced phlebotomist, or can find a vein with your eyes closed, there is a vein-finder on the market for you! Methodology to illuminate the veins varies as does the size, price, patient population served, and phlebotomist's preference.

Check out these vendors if you are tired of trial and error methods.

Accuvein 816.298.6991 www.accuvein.com
Carolina Liquid Chemistries 336.722.8910
(website address too long to list!)
Children's Medical Ventures 800.345.6443
Luminetx 910.252.3752 www.luminetx.com
Sharn Inc. 800.325.3671 www.sharn.com

TransLite 281.240.3111 www.veinlite.com
Venoscope 800.284.7655
www.venoscope.com

✓ **Artificially low WBC:** A case study in the March 2009 issue of Lab Medicine highlighted the possibility of a patient's automated white blood cell (WBC) count being falsely low due to EDTA-dependent leukoagglutination. This phenomenon seldom occurs in patients with normal WBC counts, it can be seen in patients with infection, autoimmune disorders, alcoholic liver disease and lympho-proliferative disorders. WBC agglutination is seen on the peripheral blood smear (should be done on a high WBC count). To obtain an accurate WBC count, the authors suggest the patient sample be recollected in a tube with sodium citrate or heparin as the anticoagulant. They state "since the anticoagulant used is in liquid form, the correction for dilution must be made before reporting the final leukocyte count."

✓ **Collecting / processing skin & nail samples for fungal detection:** Susan E. Sharp, PhD (DABMM) discussed proper methods for collection and detection in the February 2009 issue of MLO. Dr. Sharp's suggestions:

Nails: disinfect with alcohol gauze pads and remove crumbly debris directly under the nail near the tip. For subungual onychomycosis, collect the subungual debris close to the nail bed junction. For superficial white onychomycosis (nail plate dorsal surface), collect the deeper layers after scraping away the top nail layers.

Skin lesions: clean the skin with alcohol or sterile water (if the patient is allergic to alcohol). Use a scalpel to scrape the epidermal scales from the lesion's active borders. For vesicular dermatophytic disease, remove the tops of the vesicles with sterile scissors. Specimens can be observed microscopically after placing in 10% KOH on a clean glass slide, coverslipping, gentle heating, and waiting

for the non-fungal cells to clear. Smears can be enhanced with brighteners such as a 0.1% solution of calcofluor white added to the KOH. Specimens can be cultured for dermatophytes using a test kit and following the manufacturer's instructions for plating, incubating and reading.

✓ **Using the CLSI guideline to establish reference intervals:** The Clinical and Laboratory Standards Institute's (CLSI) document *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory* (C28-A3) was published in November 2008. In the February 2009 issue of Lab Medicine some recommendations for using this document were listed by Paul S. Horn, PhD; Gary L. Horowitz, MD; and Amadeo J. Pesce, PhD. For example:

If you use 20 normal individuals to establish or verify an interval, no more than two results can be outside the proposed range. Although the document strongly recommends 120 samples in each appropriate patient population (age, race or gender), small facilities find this difficult. There are ways to combine data from several small facilities for statistical accuracy.

When you change instruments or methods, the reference intervals must again be determined.

There are several concepts to consider. For some tests (A1c) accuracy is more clinically significant than a "normal" range. There is a target decision limit. Is your method accurate at that point? You can use fewer than 120 samples to establish the intervals if your method is "robust". Dr. Horowitz states "If people reading this article would make the effort to collect samples from just 20 reference individuals, I'll guarantee that most of them will discover their CK reference intervals are too narrow."

✓ **Watch for chronic kidney disease:** In the May 19, 2009 issue of Advance is an article reviewing a study by Quest Diagnostics which concludes persons with diabetes or

hypertension are not tested adequately for chronic kidney disease. There were significant state differences in the number of tests performed for patients with diabetes and hypertension. For example, 0.5% of people in Iowa with hypertension were tested for chronic kidney disease compared with 26.3% in Utah. The study's authors, Herman Hurwitz, MD and Harvey W. Kaufman, MD, feel Glomerular Filtration Rate (eGFR) is the most accurate test to detect and monitor kidney function.

✓ **Panbio West Nile Virus IgM Capture ELISA:** Inverness Medical Innovations Australia (IMIA) received complaints of false positive test results with their West Nile virus test. After investigation the company sent a clarification letter to their customers. The letter detailed points in the "Intended Use" and "Test Limitations" sections of the package insert. Some of these include:

Intended use: "as an aid in the clinical laboratory diagnosis of West Nile virus infection in patients with clinical symptoms consistent with encephalitis / meningitis."

"Assay performance characteristics have not been established for testing cord blood, neonate, prenatal screening, cerebro-spinal fluid, nor for use with automated instruments."

"Assay performance characteristics for general population screening (no symptoms of meningioencephalitis) have not been established."

Test Limitations: "The assay performance characteristics have not been established for visual result determination."

"Results from immunosuppressed patients must be interpreted with caution."

"Cross-reactivity has been noted in specimens containing rheumatoid factor (RF). Reactive results must be reported with a caution

statement regarding possible cross-reactivity with RF.”

“Serological cross-reactivity across the flavivirus group is common (i.e. between Saint Louis encephalitis, dengue 1, 2, 3 & 4; Murray Valley encephalitis, Japanese encephalitis, and yellow fever viruses). These diseases must be excluded before confirmation of the diagnosis.”

For additional information contact Katrina Feidler, Director, Regulatory Affairs for Inverness Medical.

2 Research Way, Princeton, NJ 08540

Phone: 609.627.8038

katrina.fiedler@invmed.com

Always read the entire package insert carefully for each test you use.

☆ Feature ☆

APHL Global Health Program Utah and Mozambique



February 12, 2009 the staff at the Utah Public Health Laboratories (UPHL) and David Sundwall, MD, Department of Health Director, welcomed Cidália G. Tembe and Márcia M.

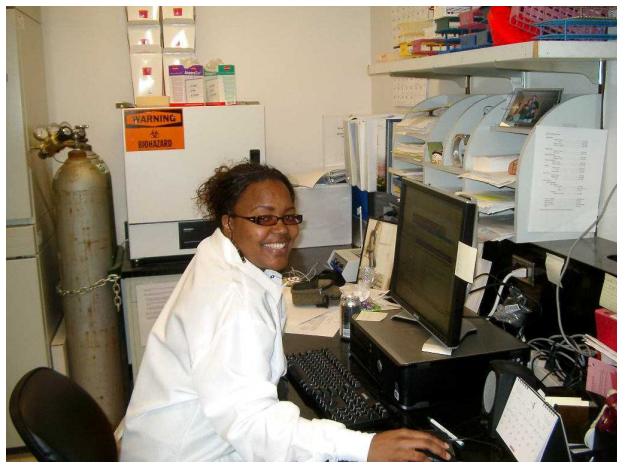
Munguambe from Maputo, Mozambique to Salt Lake City, Utah. The snow covered Utah mountains contrasted vividly with the pristine beaches on the Indian Ocean at Maputo. With money provided by the President’s Emergency Fund for AIDS Relief (PEPFAR), Cidália and Márcia were able to complete a 10 week internship in the UPHL.



In Mozambique one of the biggest challenges facing the country is lack human resources. In the laboratories it is the same. They are in great need of adequately trained personnel. One of the ways to combat this shortage has been to train basic science degree graduates (e.g. "biologists") with an intensive course in Medical Technology and bring them into the labs. This was the idea behind the training at Miami Dade College, where 12 "biologists" who were currently working in labs in Mozambique were brought to Miami for a 12-week intensive course in the major aspects of diagnostic laboratory medicine. The follow-up to this training was a 2-3month 'internship' in one specialty area at a public health or clinical lab in the US to gain hands-on experience. Participating laboratories include; Utah State PHL, LA County PHL, Michigan State PHL, Virginia State PHL, University of Miami Hospital/Miami Dade College, and Children's Hospital Philadelphia.

The emphasis of this training is “good laboratory practice - quality and safety”. It is hoped after completing training the 'biologists'

will have a greater understanding of not only the theory behind the tests that they are performing but also how to accomplish quality testing in a safe and competent manner and be able to trouble-shoot when problems arise. APHL will continue to work with the 12 biologists in Mozambique to improve testing in their laboratories.



During their 10 week internship in the UPHL Cidália and Márcia experienced clinical applicability in laboratory management skills, training in Immunology, Level A Bioterrorism, Mycobacteriology, Routine Microbiology, general laboratory and biological safety practices, virology, and water microbiology. They took a NLTN course on packaging & shipping division 6.2 materials with other laboratory professionals from Utah.

Outside training by several of the UPHL laboratory partners included parasitology at ARUP; anaerobic bacteriology at IMC; clinical health care in chemistry and hematology at Intermountain Layton Clinic; routine microbiology at Microculture Inc., UUHN Redwood Clinic, and Intermountain Salt Lake Clinic; enteric pathogens at University of Utah Medical Science Student Lab; and media preparation at Weber State University. These hands-on experiences enhanced the intensive UPHL training program. After hours UPHL staff showed Cidália and Márcia many of the local sites – including

American Bison on Antelope Island in the Great Salt Lake. A farewell western barbecue climaxed the cultural exchange. We miss our new friends, but keep in touch through email.



*"You make a living by what you get.
You make a life by what you give."
Winston Churchill*



CLIA BITS

ADDITIONAL WAIVED TESTS:

- ° Jant Pharmacal Accutest Immunological Fecal Occult Blood & URS Urine Dipstick Reader
- ° Abaxis Piccolo Renal Function Panel & Metlyte * Panel Reagent Disc for Blood Chemistry and Express Chemistry Analyzer
- ° Amedica Biotech Drug Screen & Home Drug Test Cup
- ° CLIA Waived *H. pylori* whole blood rapid & X Multiple Drug Cup Test

- ° Siemens Clinitek Status Urine Chemistry Analyzer for urine hCG
- ° Roche Diagnostics Accutrend Plus System for glucose and cholesterol
- ° Aventir Biotech LLC Home Check Multiple Drug Cup Test
- ° Syntron Bioresearch Quikscreen Multi Drug Cup Test
- ° MEC Dynamics Avie A1c Test System

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CLIA Questions & Answers

Q: Is the Abbott iSTAT Chem8+ Cartridge waived complexity for capillary specimens?

A: NO. The Cartridge was approved by FDA as waived for whole blood venous samples.

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Multiple Site CLIA Certificates

Reference: S & C 09-23

In addition to the multi-site exceptions listed on the CLIA application (CMS 116 section V Multiple Sites) a home health care or hospice agency with many “branches” or “multiple locations” may have one certificate as long as all the branches / multiple locations have the same HHA number. If the same company has Home Health and Hospice at the same address, they can have the same CLIA number only if they have the same provider number.

The exceptions on the CMS 116 include “mobile lab” (mobile units moving from site to site providing testing, health screening fairs, or other temporary locations which have a designated home base); not-for-profit government labs that perform no more than 15 types of moderate and / or waived tests – all testing sites combined); and hospital labs on the same campus owned and operated by the same entity.

Equals
"1 kilogram of falling figs: 1 Fig
Newton"

Quality Assessment Spotlight



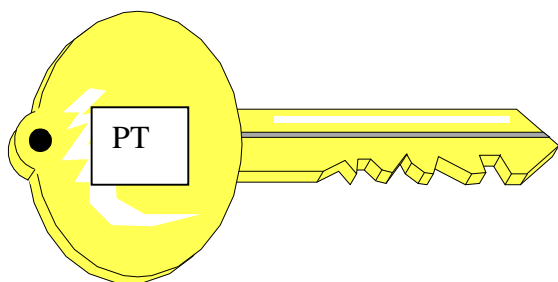
A case study was reported in the January 2009 issue of ASCLS Today. A 35 year old recent immigrant from El Salvador presented with a simple gastrointestinal upset and no other symptoms. The patient just felt “out of it”. Routine lab tests (UA, CBC, CMP) were normal except for a high chloride and negative anion gap. Since a negative anion gap is not physiologically possible, a root cause analysis was done.

Pre-analytic error was ruled out (i.e. phlebotomist drew sample in wrong tube then transferred specimen to correct tube). Since no other patient was having a similar problem, the lab looked for test interference (analytic). The lab was using an ISE method to do chloride. Halogens can have similar properties to chloride. The lab narrowed the field to bromine. The patient was consulted and the clinician discovered he was taking a medication from El Salvador to help him sleep. The medication contained sodium bromide. The patient’s blood bromide level was 70 mg/dL. Problem solved.

Kudos Tracy Park and staff

Ponderables:

If you drink Pepsi at work in the
Coke factory, will they fire you?



Proficiency Test Failures

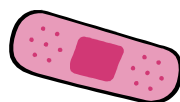
✚ Investigate any score <100% to find a potential problem before you are unsuccessful (fail 2 of 3 consecutive events).

✚ When you fail two analytes or subspecialties in 2 of the previous 3 events, notify the state agency and stop patient testing. Fix the problem, pass 2 PT testing events (you can usually purchase off cycle samples from one of the PT providers), check your patient results during the failure time frame and notify the state agency of your progress.

✚ Don't ignore "near" misses or always blame the company for sending "bad" samples.

✚ Don't assume your patient results were okay because the controls were in range. Look for the PT failure cause.

There is a proficiency test quality assurance aid available on our website at <http://health.utah.gov/lab/labimp>.



SAFETY

Recall – Triage(r) Cardiac Panel

Biosite initiated a voluntary, nationwide recall of one lot of Triage(r) Cardiac Panel kits (Catalog No. 97000HS, Lot #W44467B). Contact Biosite at 877.441.7440 option 2 (available 24/7).

Any adverse patient outcome due to this product's use should be reported to FDA at 800.332.1088 or www.fda.gov/medwatch.

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Monitoring Hazardous Chemical Exposure in the Histology Lab

OSHA regulations found in 29 CFR 1910 Subpart Z require exposure monitoring at least initially when starting a new test procedure using chemicals from the Table Z-1 list. Monitoring must be done additionally if there is an accident / spill, change in facility conditions that might increase exposure (trouble with the air handling system), or an employee shows symptoms. The most common chemicals from the list in use in the histology lab are xylene and formaldehyde. Refer to the OSHA regulation for permissible exposure limits and appropriate testing methods for your chemicals.

You may control exposure with proper personal protective equipment (PPE = lab coat, gloves, chemical splash goggles, respirators); engineering controls (proper ventilation by using hoods, increasing the room air exchanges per hour); and good work practices (using minimum volumes, storing chemicals in a vented cabinet or room, organizing work for a minimum chemical exposure).

PPE – safety glasses and face shields do not adequately protect against splashes as they leave spaces between the plastic and skin.

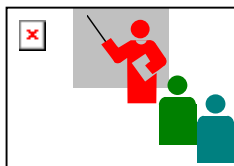
High quality nitrile gloves are adequate for most purposes. For long term exposure, it is necessary to use industrial gloves with a good enough rating necessary to protect you from the chemical you are using.

If an employee is sensitized to a particular chemical, OSHA's respiratory protection standard requires medical evaluation (as well as annual fit testing) for any employee wearing a respirator (this includes N-95 masks).

Engineering Controls: ANSI (American National Standards Institute) recommends hood face velocity be 80-100 linear feet per minute.

Work Practices: Be certain your written chemical hygiene plan for "Z-list" chemicals you use has information on how to handle different size spills. Keep monitoring records, employee evaluations and fit test results for as long as the OSHA standard requires.

CONTINUING EDUCATION



Labs are Vital

Video: "Silent Treatment"
http://labsciencecareers.com/lab_sciences.

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ASCLS

Video: "A Life Saved: Laboratory Professionals Make a Difference"
<http://www.ascls.org/leadership/ppc/index.asp>.

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CDC

There is a link on their home page for the Public Health Image Library www.cdc.gov.

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NLTN

Free web cast "Influenza Virus H1N1 (Swine-like) and the Clinical Laboratory" available 24/7 from May 13 through November 13, 2009. Register at www.nltm.org/206-09.htm or call 240.485.2727.

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APHL

Infectious disease series continues in June with "Eradication of Staph aureus and MRSA Prior to Inpatient Surgery", "Importance of HSV type-specific testing in genital herpes diagnosis" and "2009 Influenza Update". Contact Rebecca Christiansen at rchristiansen@utah.gov for information.

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LEND

This program offers online CEs that are PACE approved. Contact Chris Triske, MS, MT(ASCP) at 701.777.2404 or visit <http://www.medicine.nodak.edu/lend>

Understanding Our Universe

"In the beginning the Universe was created. This has made a lot of people very angry and been widely regarded as a bad move."

Douglas Adams